

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 10/618,223 Confirmation No.: 4411
Applicant(s): Mangiardi et al.
Filed: 07/11/2003
Art Unit: 3736
Examiner: Kristin D. Rogers
Title: LUMEN-MEASURING DEVICES AND METHOD

Docket No.: 047956/288167
Customer No.: 00826

Mail Stop Appeal Brief-Patents
Commissioner for Patents
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REPLY BRIEF UNDER 37 CFR § 41.41

Applicant appreciates the thorough review of the Appeal Brief as evidenced by the Examiner's Answer mailed on September 24, 2009. In light of the Examiner's Answer, Applicant submits rebuttal arguments to address the rejections, as well as clarify arguments previously submitted in the Appeal Brief.

a) Summary of Claimed Subject Matter

In the Examiner's Answer, the Examiner finds that the Summary of Claimed Subject matter is deficient because FIGS. 14-18 are allegedly not relevant to the claimed invention. Quite the contrary, FIGS. 14-18 are very relevant to the claimed invention, as Applicant submits that independent Claims 1, 7, 24, and 37 read on the embodiment shown in FIGS. 14-18. Indeed, as discussed below, the rejection under 35 U.S.C. §112, first paragraph, is disputed and turns on whether the original disclosure supports claims reading on both of the embodiments shown in FIGS. 1-18. Therefore, Applicant respectfully submits that FIGS. 14-18 are relevant to this appeal and that the Summary of Claimed Subject matter is accurate.

b) The Rejection of Claims 5, 12, and 41 under 35 U.S.C. §112, ¶1 is Overcome

The Examiner rejects Claims 5, 12, and 41 for allegedly failing to comply with the written description requirement. In particular, the Examiner contends that use of the term “adjacent does not define the same spatial limitations as ‘substantially flush with’” when describing different embodiments, and the failure to illustrate a cross-sectional view provides evidence that the original disclosure does not describe legs of the embodiment shown in FIGS. 14-18 having inward facing surfaces that are in flush contact with one another along their entire length.

Applicant continues to disagree with this rejection, as Claims 5, 12, and 41 are supported by the original specification. The Examiner appears to be looking for explicit disclosure within the specification that describes the legs shown in FIGS. 14-18 as being substantially flush along their lengths. However as noted in the Appeal Brief, the criteria for determining whether the written description requirement is satisfied is that “each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.” See MPEP §2163 (emphasis added). In addition, “the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” See MPEP §2163.03 (emphasis added). The only difference between the embodiment shown in FIGS. 1-13 and the embodiment shown in FIGS. 14-18 is that the distal ends of the legs are not coupled or coupled together, respectively. Thus, although not explicitly disclosed, the present application implicitly and/or inherently provides with reasonable clarity to one of ordinary skill in the art that the legs are configured to extend flush to one another when constrained within the exterior conduit, regardless of whether the legs are coupled at their distal ends or not. Clearly, this would be a reasonable interpretation of the original disclosure by one of ordinary skill in the art. Therefore, Applicant respectfully submits that the rejection of Claims 5, 12, and 41 under §112, first paragraph, is overcome.

c) The Rejection of Independent Claims 1, 7, 24, and 37 under 35 U.S.C. §103(a) over Jain in view of Colvin, Haddock, Doi, and Baxter-Jones is Overcome

Applicant submits that there is no motivation to combine Jain and Haddock and modify Jain to include inward facing surfaces of the legs that are in flush contact with one another between their proximal and distal ends when the measurement assembly is closed within the exterior conduit, as recited by independent Claims 1, 7, 24, and 37. In the Examiner's Answer, the Examiner finds that the requisite motivation to combine Haddock with Jain stems from each reference disclosing "structures that expand inside a tubular member to contact the tubular member and measure some aspect of the tubular member."

However, Applicant submits that the references cannot be combined if the combination would render Jain unsatisfactory for its intended purpose or if the references teach away from such a combination (see MPEP §2145(X)). FIG. 2 of Jain shows that the wire filaments (44) fan outwardly within the sheath (22), and Jain explicitly discloses that the wire filaments mount to a catheter (40) and fan outwardly in a conical fashion but are restrained from fully doing so by the sheath.

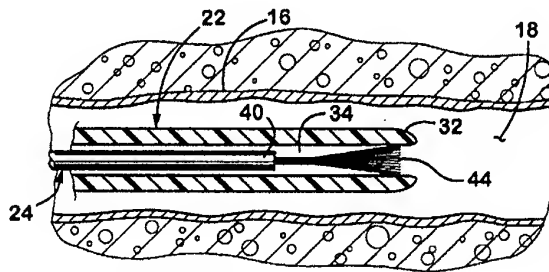


Fig. 2

Thus, Jain clearly shows that the thin wire filaments are biased outwardly within the sheath and that the configuration of the catheter and wire filaments would prevent the filaments from lying flush to one another along their entire lengths as shown in FIG. 2 of Jain. Jain discloses thin wire filaments, while Haddock discloses large fingers integrally formed from a cylindrical structure. In addition, Haddock discloses that the fingers include sensors on their outer surfaces that are configured to contact the tissue, while Jain discloses that rather than the outer surfaces, the distal ends of the wire filaments contact the tissue to measure the diameter of the lumen.

Thus, Jain teaches away from filaments lying flush to one another along their lengths given that Jain discloses outwardly fanning filaments rather than discrete sections of a cylinder and that the diameter is measured based on the distal tips of the filaments contacting the lumen rather than their outer surfaces. Therefore, there is no teaching or suggestion to modify Jain to include wire filaments that have inward facing surfaces that lie in flush contact with one another between their proximal and distal ends, and independent Claims 1, 7, 24, and 37 are patentable for at least this reason.

Moreover, Applicant submits that there is no teaching or suggestion to combine Jain, Doi, and Baxter-Jones and modify Jain to include an exterior conduit that is configured to engage measurement markers defined on the lumen-facing surfaces of a plurality of legs to provide an indication of a diameter of the target segment, as recited by independent Claims 1, 7, 24, and 37. The Examiner argues that Baxter-Jones is analogous art because it relates to a measuring device for measuring parts of the body. Even if analogous art, Applicant does not believe that there is any teaching or suggestion to modify Jain and Doi in view of Baxter-Jones. The devices of Jain and Doi may be used to measure a diameter of a target segment using radially expandable legs, while the device of Baxter-Jones functions quite differently and is employed to measure the length of a cervix using an axially displaceable measurement indicator. One of ordinary skill in the art would not look to Baxter-Jones to support the modification of providing engageable measurement indicators on a plurality of radially expanding legs especially where Baxter-Jones only discloses a ring-shaped indicator that slides along a cylindrical member. Although the Court in *KSR Int'l Co. v. Teleflex Inc.* found that the teaching, suggestion, and motivation test should not be rigidly applied, some teaching, suggestion, or motivation and a reasonable expectation of success are needed in order to properly combine references. *See* MPEP §2143 (citing *KSR*, 550 U.S. ___, 82 USPQ2d, 1385 (2007)). Thus, even if Baxter-Jones relates to measurement indicators, the Examiner has failed to provide the requisite teaching, suggestion, or motivation and a reasonable expectation of success to modify the references in the manner proffered by the Examiner.

Furthermore, the Examiner believes that although Doi discloses measurement markers that are painted on the outer surface of the strips, Doi discloses that the scale may be modified in

various manners depending on the intended use of the device, which allegedly provides motivation to modify the painted lines to include measurement markers that can be engaged by an exterior conduit. The Examiner goes further to state that it would have been obvious to one of ordinary skill in the art to provide measurement markers carved into or projecting from a measurement tool, especially where Doi only discloses visual indicators. However, the Examiner provides no evidence supporting this conclusory statement. Applicant respectfully submits that such a rejection amounts merely to a general conclusory statement without a clear articulation of the reasons why the claimed invention would have been obvious. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007), *quoting In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be *some articulate reasoning* with some rational underpinning to support the legal conclusion of obviousness” (emphasis added)). The scales or alleged measurement markers of Doi are not configured to engage an outer exterior conduit, while the wire filaments of Jain do not include measurement markers at all. Moreover, Baxter-Jones discloses a slidable indicator for axial movement along an elongated member rather than an exterior conduit for engaging measurement markers on a plurality of legs as described above. Thus, Applicant submits that there is no motivation or suggestion to modify the visual indicators of Doi and the wire filaments of Jain to include measurements markers that can be engaged by an exterior conduit in light of Baxter-Jones.

The Examiner contends that any conclusion of obviousness based on hindsight is proper as long it only takes into account knowledge of one of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from the Applicant's disclosure. However, because the Examiner has failed to provide any cited reference that teaches or suggestions an exterior conduit that is configured to engage legs having measurement indicators on their lumen-facing surfaces in order to determine a diameter of a target segment, as recited by independent Claims 1, 7, 24, and 37, the Examiner has used knowledge gleaned only from Applicant's disclosure.

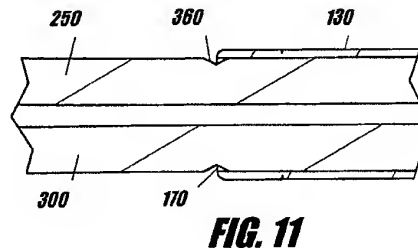
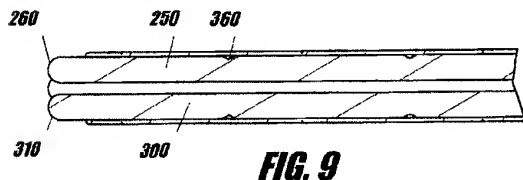
Accordingly, Applicant submits that the rejection of independent Claims 1, 7, 24, and 37 under 35 U.S.C. §103(a) is overcome. The remaining dependent claims depend from and further

patentably distinguish Claims 1, 7, 24, and 37 and are also allowable for at least those reasons discussed above.

d) Dependent Claims 45, 48, 52, and 56 are Separately Patentable

Applicant disagrees that Baxter-Jones discloses Claims 45, 48, 52, and 56, which recite that the measurement markers of the legs comprise detents defined therein. Although Baxter-Jones discloses detents (1130), the detents are not defined in the elongated member (1102) but, rather, *project outwardly* from the outer surface of the elongated member. Page 10, lines 5-6 of the present application discloses that the measurement markers may be “carved into the legs so as to form detent or lip catches,” which is nowhere taught or suggested by Baxter-Jones or any of the remaining cited references.

The Examiner argues that Baxter-Jones uses the term “unidirectional detent” to describe its projections, that the definition of “therein” does not require the detents to be formed within the legs, and that the definition provided in the specification does not support Applicant’s assertion that Baxter-Jones does not teach or suggest measurement markers comprising detents formed therein. Applicant notes that terms used by Baxter-Jones’ or dictionary definitions of “detent” or “therein” is irrelevant for purposes of interpreting the meaning of detent when the specification clearly provides a definition of detent. In particular, the specification discloses that the detents are carved into the legs. Moreover, FIGS. 9 and 11 of the present application clearly show that the detents (360) or lip catches are formed within the legs as shown below.



Applicant also notes that although the claims are to be given their broadest interpretation, this interpretation must be reasonable consistent with the specification (see MPEP §2111). Instead of using the specification to interpret the claim language, the Examiner is looking to the prior art

and dictionary definitions, which is inconsistent with Applicant's ability to be its own lexicographer. Therefore, Applicant submits that because the claims require that the detents be formed within the legs, none of the cited references, taken alone or in combination, teaches or suggests Claims 45, 48, 52, and 56.

e) The Rejection of Dependent Claims 46, 49, 50, 53, 54, and 57 under 35 U.S.C. §103(a) is Overcome

As noted in the Appeal Brief, Applicant submits that Baumann is non-analogous art for purposes of an obviousness rejection under 35 U.S.C. § 103(a). The Examiner argues that "Baumann is analogous art as it is part of the art of measurement devices." Applicant strongly disagrees given that Baumann is not at all related to measurement devices and provides no means for determining any measurement. In fact, Baumann is not even used to measure the length of the hair but, instead, provides a means to incrementally adjust the length of hair being cut to a predetermined length such that there is not even the pertinence of obtaining a measurement. Applicant notes that the U.S. classification for Baumann is 30 which relates to Cutlery. Cutlery devices are not "reasonably pertinent" to solving the problem of measuring the lumen or a target segment within the human body. Nor would one of ordinary skill in the art look to cutlery devices in order to solve the problem of measuring a lumen or target segment. Therefore, Applicant fails to appreciate the relevance of "cutlery" devices to medical devices used to determine a measurement within the human body and submit that Baumann is non-analogous art and should not be relied upon as prior art against the claimed invention.

Furthermore, Applicant respectfully submits that there is no motivation to modify any of the cited references in light of Baumann to include a lip extending from an inner surface of an exterior conduit that engages detents defined in the legs. The Examiner believes that one of ordinary skill in the art would have known to substitute the detents (notches 49 of FIGS. 6 and 7) of Baumann for the projection-type detents of Baxter-Jones. Again, Applicant respectfully submits that this statement is merely conclusory without a clear articulation of the reasons why such a modification would have been obvious. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007), *quoting In re Kahn*, 441 F.3d 977, 988 (CA Fed.

2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be *some articulate reasoning* with some rational underpinning to support the legal conclusion of obviousness” (emphasis added)). There is simply no reason to modify Baumann in such a manner where Baxter-Jones discloses outwardly extending detents, while Baumann discloses inwardly extending notches. Therefore, Applicant respectfully submits that none of the cited references, taken alone or in combination, teaches or suggests Claims 46, 49, 50, 53, 54, and 57.

In any event, even if Baumann is erroneously combined with Jain and the remaining cited references, Applicant submits that Baumann does not teach or suggest that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs. The Examiner finds that either the air guide (46) or the outer end (57) is a lip that extends from an exterior conduit. However, the air guide is not a lip configured to engage a detent but, rather, is used to change the direction of an airstream (see FIG. 2 and col. 3, line 59 – col. 4, line 8). Thus, Applicant does not agree that the air guide is a lip configured to engage detents. Moreover, Baumann does not disclose that the inner surface of the wall (54) or alleged exterior conduit includes a lip that protrudes from its inner surface. Rather, a detent lever (52) is pivotally attached to the outer surface of the wall about pivot (53) such that the alleged inner surface of the wall does not include a lip protruding therefrom. Therefore, neither Baumann, nor any of the remaining cited references, teaches or suggests Claims 46, 49, 50, 53, 54, and 57.

CONCLUSION

For the above reasons as well as for the additional reasons set forth in the Appeal Brief, it is submitted that the rejections of the pending claims are erroneous and reversal of the rejections is respectfully requested.

Respectfully submitted,



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